Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

TRACY DIONNE KNOX and HERBERT KNOX,
Petitioners

V.

SANDOZ PHARMACEUTICALS CORPORATION,
Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

What is the threshold standard to be applied by the trial court as "gatekeeper" to scientific evidence under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) and Fed. R. Evid. 702 when the scientific evidence is well-grounded, but innovative, and the proposition is too particular, too new, or of too limited interest to be published or otherwise satisfy the enumerated indicia of reliability found in Daubert?

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PETITION FOR WRIT OF CERTIORARI

Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Fifth Circuit entered in this case March 10, 1997.

OPINIONS BELOW

The opinions of the District Court are unreported and are reproduced in the Appendix as follows: Order Granting Plaintiffs' Motion for Leave to Amend Complaint and Reopening Discovery, App.-2; Order Partially Granting Plaintiffs' Motion for Reconsideration, Partially Granting Defendant's Motion in Limine, and Partially Granting Defendant's Motion for Summary Judgment, App.-6; Order Granting Defendant's Motion for Summary Judgment on Plaintiffs' First Amended Original Complaint, App.-18; Final Judgment, App.-19. The opinion of the Court of Appeals is unreported and is reproduced at App.-20.

JURISDICTION

The order of the District Court was entered July 11, 1996. App-18. The final judgment of the District Court was entered July 15, 1996. App-19. The judgment of the Court of Appeals was entered March 10, 1997. App.-20. No petition for rehearing was filed with the Fifth Circuit Court of Appeals. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RULES INVOLVED

Rules 104 and 702 of the Federal Rules of Evidence are reproduced at App.-25.

STATEMENT OF THE CASE

Petitioner, Tracy Knox, ingested Parlodel for the purpose of suppressing post-partum lactation. After she suffered stroke-like symptoms later diagnosed as tardive hemidystonia, she and her husband filed suit in a Texas state court against the manufacturer of Parlodel, Sandoz Pharmaceuticals Corporation ("Sandoz"). Invoking diversity jurisdiction under 28 U.S.C. § 1332, Sandoz removed this case to the United States District Court for the Southern District of Texas. The District Court, under this Court's opinion in Daubert and Fed. R. Evid. 104 and 702, excluded the testimony of the Petitioners' treating physician and granted summary judgment in favor of Sandoz. The Fifth Circuit Court of Appeals, exercising its jurisdiction under 28 U.S.C. § 1291, affirmed.

A. The District Court's Ruling

1. Credentials and Relevance Were Undisputed.

There can be no question but that Dr. Inbody, the expert witness who was excluded from testifying, is highly qualified as an expert regarding Parlodel and its effect on human patients. The trial court's remarks during the Daubert hearing illustrate this quite well:

> This is an extremely able, respected physician who was careful in his diagnosis, conclusion and concern for his patient, who in fact has not only diagnosed this cause but believes it to be a cause so much so that that's the way he treats his patient, I mean he believes it to such a

> degree that he has implemented that belief in the course of her treatment. I mean it's just not, "This is my opinion, I'm an expert, now I'm picking up my expert fee and I'm going home." This is a lady that he's treated. So, and he has impeccable credentials as a neurologist. I mean I haven't, don't know many neurologists but it sounds like that he has impeccable credentials. I don't have him to compare with other neurologists but he certainly is, what is it, Chief resident of Baylor Medical College? I mean, I didn't know what institution Baylor was associated with, perhaps none, but it is certainly well known to me as being a very fine institution. He has enormous experience. He has been a classroom teacher, he's been a researcher, he's, the man knows what he's talking about when he performs his doctor's , as a doctor of neurology. Anybody that had him would be, I think, darned lucky to have him as a physician, and I haven't seen anything to the contrary and you haven't offered me anybody that says to the contrary.

App-24.

Likewise, relevance is undisputed. Dr. Inbody has testified that Parlodel is the cause of Tracy Knox's dystonia in terms sufficient to satisfy the test for legal causation. App.-23.

2. The Trial Court Rejected the Testimony.

After the Daubert hearing, the trial court set out the following ruling, despite its acknowledgment that the Daubert analysis concerns itself with the underlying principles and methodologies of the expert, rather than ultimate conclusions:

> The court finds that Dr. Inbody possesses excellent credentials and experience in the field of neurology. In spite of the plausibility of his conclusions, however, the court is not prepared at this time to permit Dr. Inbody to testify as an expert under the standards set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786, 2796-97 (1993). There is a significant lack of evidence of tests, publication, rate of error, or general acceptance of Plaintiff's expert's position.

Order Granting Plaintiffs' Motion for Leave to Amend Complaint and Reopening Discovery, App.-2 (emphasis added).

While acknowledging that the Daubert criteria are flexible, the trial court continued to exclude Dr. Inbody's testimony with respect to the causation of tardive dystonia because the conclusion did not fit the four "tests" of Daubert and because the probative value was deemed to be outweighed by the danger of unfair prejudice. Order Partially Granting Plaintiffs' Motion for Reconsideration, Partially Granting Defendant's Motion in Limine, and Partially Granting Defendant's Motion for Summary Judgment, App.-6.

The trial judge later stated his reasoning on the record:

> [F]or purposes of the record, if the Circuit would like to know what I was thinking on that, I tried to put it in the order, and while he thought, while the Doctor was expressing himself in a logical fashion, going from one level of observation and thought to another, my judgment was that if I were to rely upon the signposts of Daubert that his theory I think failed on every one of those four criteria that Daubert likes us to examine. So that's where we are.

App-16-17 (emphasis added). Importantly, at no time did the trial court cite any defects in Dr. Inbody's scientific methodology or reasoning as a basis for excluding his testimony.

B. The Court of Appeals' Ruling

The Court of Appeals, after hearing oral argument, affirmed the judgment, stating only that the trial court had not abused its discretion. App.-20.

REASONS FOR GRANTING THE WRIT

A. Overview

This case is the antithesis of Daubert; it falls at the opposite end of the legal/scientific evidence spectrum. As such, this case falls in a gap expressly acknowledged, but left wide open, after this Court's opinion in Daubert. This Court

needs to fill that gap and provide the trial courts with appropriate guidelines for the exercise of their gatekeeping role in scientific scenarios that are not as well developed as they were in Daubert.

While the Daubert opinion stated that there may be scientific evidence that is innovative and too new or of too limited interest to prompt or receive peer review, the only admonition to trial courts was to be "flexible." This standard fails to provide the trial court with any guidance in reviewing the type of expert testimony proferred here for scientific reliability. As a result, the enumerated "signposts" of the Daubert opinion can be, and were, applied rigidly and arbitrarily to exclude testimony.

Without guidance from this Court regarding this type of evidence, the trial courts too easily fall back on the "signposts," and the courts of appeals too easily affirm the district court's "exercise of discretion." Parties then find their cases summarily adjudicated, not because they had unreliable scientific evidence but because the legal standard applied did not accommodate the type of evidence required by the case.

B. The Contrast Between This Case and Daubert

In Daubert, a number of scientific experts were hired for the express purpose of finding a causal relationship between Bendectin and birth defects. Here, Dr. Inbody is Tracy Knox's treating physician, who has not asked for any compensation for his testimony. In the course of treating Tracy Knox, Dr. Inbody had fought "tooth and nail" against the idea that Parlodel had caused Tracy Knox's condition. Only through the painstaking elimination of other causes did Dr. Inbody arrive

at what he now considers the "obvious" relationship between Parlodel and tardive dystonia in an otherwise healthy patient.

In Daubert, the question of whether Bendectin caused birth defects had been studied exhaustively. High quality studies had refuted the hypothesis that Bendectin was a teratogen, thus appearing to preempt the plaintiffs' case. Here, because of the rarity of the reaction in lactating females, doctors and scientists have not studied the specific relationship of Parlodel to sustained tardive dystonia in otherwise healthy patients.

Sandoz does not come to trial armed with any "vast body" of scientific evidence expressly disproving the Knox's allegations. Rather, Dr. Inbody has used well-established, generally accepted scientific and medical knowledge and studies regarding Parlodel, Parkinson's patients, and other similar drugs to fill what would otherwise be a gap in scientific understanding. Sandoz does not have any superior scientific evidence of a quality to eliminate the fact question on causation, neither does it have appropriate evidence to challenge Dr. Inbody's methodology. In fact, Sandoz offered no expert evidence whatsoever at the Daubert hearing.

The trial court rigidly applied the Daubert criteria, without taking into consideration this Court's acknowledgment that the criteria were flexible and would have to be adjusted to accommodate novel conclusions. The underlying principles that Dr. Inbody uses are well-established, and satisfy the Daubert "test." In fact, he characterizes much of it as obvious, and apparent in Sandoz's own literature. Only the conclusion is new; and this Court expressly considered that such situations would call for different criteria.

By the exclusion of Dr. Inbody's testimony, Tracy Knox is denied any chance of proving causation and obtaining compensation for her injuries, simply because she is the first patient to have a competent and insightful treating physician work so doggedly and thanklessly to find the explanation for her rare condition.

The experts who were rejected in Daubert spent 10 years as hired guns to "swim against the tide," using questionable methodologies, without gaining any acceptance in the scientific community. To the contrary, Dr. Inbody, a treating physician, filled a small vacuum using well-established scientific knowledge. Furthermore, Dr. Inbody's scientific insights in this regard were no more than three months old at the time of the Daubert hearing in this case. Thus his theory has not yet had much opportunity to gain acceptance in the scientific community, and certainly has not been rejected. In fact, Dr. Inbody may not be able to gain acceptance for his ultimate conclusion in the scientific community until he can prove it through an autopsy after Tracy Knox's death.

C. The Trial Court Was Without Adequate Guidelines for Satisfying its Daubert Role.

The trial court indicated, as early as the argument immediately following the evidentiary Daubert hearing, that he would apply an inflexible approach. "The United States Supreme Court has set some very stringent guidelines on the admission of scientific testimony." App.-22. The trial court indicated that only the four "tests" of Daubert were at issue. App.-8-9. In its Order on the Motion for Reconsideration, the trial court wrote, "Although Daubert creates a flexible approach, the testimony in the present case does not clearly

satisfy any of the factors discussed in Daubert." Order, App.-10. Again, in explaining its ruling, the trial court stated, "my judgment was that if I were to rely upon the signposts of Daubert that his theory I think failed on every one of those four criteria that Daubert likes us to examine. So that's where we are." App.-17 (emphasis added).

The trial court's application of Daubert to the medical and scientific evidence in this case erroneously places a higher burden of scientific proof than is required by the rules of evidence. Viewed on a comparative or relative basis, Dr. Inbody's scientific knowledge, observations, and conclusions are amply reliable and should not be rejected simply because another case, involving another drug, involved far more developed testing.

To impose that level of evidence in this case is to deny the Knoxes any recovery simply because Tracy Knox is the first patient of her kind to be identified with this Parlodel-induced dystonia. Unfortunately, the trial court considered it significant that the testing and experience that supported Dr. Inbody's conclusions came from Parkinson's patients rather than healthy lactating females. There was no evidence that the parallels between the groups that Dr. Inbody testified to were not scientifically valid. Yet, because no other scientist was corroborating Dr. Inbody's testimony, it was excluded.

D. This Case is Important Because of Its Obscurity

As this Court has surely noticed, there are no published opinions in this case that might lead astray other courts and litigants. In that sense, it might appear to be insignificant.

However, the short shrift given this case is just the thing that makes the case so alarming.

Here, the trial court describes the expert witness as an impeccably credentialed treating physician who comes to court not as a hired gun, but as a caring neurologist with a logical and compelling presentation of drug causation, under a differential diagnosis, based upon extensive experience with Parkinson's patients. App.-23-24. Yet the testimony is excluded because, the trial court believed, the four signposts of Daubert, the only available guidance, "dictated" its exclusion. App.-2, 16-17. And the Fifth Circuit merely noted its abuse of discretion standard of review and summarily affirmed.

The interests of justice call out for a review of this case so that trial courts and courts of appeal will have better guidance in their consideration of cases where the science is reliable, but the conclusion is too new and of too limited interest to trigger extensive peer review. Tracy Knox and her husband deserve the opportunity to present their expert witness to the jury for its consideration of the weight and credibility to be assigned to Dr. Inbody's testimony.

The trial courts need to be reminded that Daubert did not eliminate the "battle of the experts." An expert's opinion need not be a scientific certainty, it need not be generally accepted in the community, it need only be legitimate science.

PRAYER

For the reasons stated, certiorari should be granted and Petitioners, Tracy Dionne Knox and Herbert Knox so request.

Respectfully submitted,

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** Counsel of Record

APPENDIX

APPENDIX A

[Filed Jan. 5, 1996]

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

TRACY DIONNE KNOX	§	
AND HERBERT KNOX	§	
	§	
V.	§	CA. NO. C-94-527
	§	
SANDOZ	§	
PHARMACEUTICAL	§	
CORPORATION	§	

ORDER GRANTING PLAINTIFFS' MOTION FOR LEAVE TO AMEND COMPLAINT AND REOPENING DISCOVERY

At an evidentiary hearing held on January 3, 1996, Dr. Stephen Inbody testified that causation more likely than not exists between the drug Parlodel and Plaintiff's injuries. The court finds that Dr. Inbody possesses excellent credentials and experience in the field of neurology. In spite of the plausibility of his conclusion, however, the court is not prepared at this time to permit Dr. Inbody to testify as an expert under the standards set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2796-97 (1993). There is a significant lack of evidence of tests, publication, rate of error, or general acceptance of Plaintiffs' expert's position. In determining the admissibility of scientific evidence, the court's focus "must be

solely on principles and methodology, not on the conclusions they generate." Id. at 2797.

The court finds that counsel for Mr. and Mrs. Knox has not complied with court orders to file any necessary amendments to pleadings by June 16, 1995 and to complete all discovery by September 15, 1995. No good cause has been offered for counsel's failure to abide by court schedules for disposition of this case. The court finds that other procedural defaults by Plaintiffs' counsel have occurred to confuse the conclusion of the case.

The court has repeatedly and emphatically denied Plaintiffs' Motion for Continuance; however, the court now grants the continuance sought for the reason and on the conditions hereafter set forth.

The seriousness of Mrs. Knox's injuries and illnesses cannot be questioned. Dr. Inbody is highly credentialed and educated. Since his deposition in September, Dr. Inbody has become more convinced that Mrs. Knox's condition was caused by her taking Parlodel. Although documents were in the possession of Plaintiffs' counsel at the time of the Daubert hearing that could have been shown to Dr. Inbody at the hearing, this evidence was not shown to Dr. Inbody. The court cannot assess the significance of this evidence without Dr. Inbody's review of it. Counsel for Plaintiffs asserts without proof that he could find other witnesses to support Dr. Inbody. The court, in spite of all long and justified denials of a continuance, grants the motion to continue to protect the interests of Mrs. Knox and her husband.

Leave is further granted to Plaintiffs to file Plaintiffs' Amended Complaint. The issues raised do not significantly expand the normal issues of a products liability case.

Plaintiffs are given 30 days to file all names of additional expert witnesses to testify at trial. All documents relied upon by Plaintiffs' experts in support of their position shall be furnished to Defendant. Plaintiffs' experts will be deposed during the following 30 days, or in such time as may be permitted by the court. Defendant shall designate any of its experts not yet named within 30 days after Plaintiffs' experts have been deposed. Plaintiffs then shall have 30 days to depose these experts.

No other witnesses except these experts will be added to the witness list.

As a sanction for lack of attention to the court's scheduling order and for lack of preparation (which includes the failure of Plaintiffs to accept Defendant's offer to review documents; the failure of Plaintiffs to submit written discovery to Defendant, and the failure of Plaintiffs to obtain pertinent public documents concerning Parlodel), Plaintiffs' counsel, Cage Wavell, is ordered to attend at his sole expense a seminar on federal practice and procedure. One is sponsored by Southern Methodist University in Dallas, Texas on February 8-9, 1996. Mr. Wavell is ordered to attend that seminar unless he can show good cause why he should not attend.

ORDERED this 5th day of January, 1996.

/s/ H.W. Head, Jr.
H.W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

ENTERED ON DOCKET
JAN. 5, 1996
BY MICHAEL N. MILBY,
CLERK OF COURT

APPENDIX B

[Filed Jun. 11, 1996]

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

TRACY DIONNE KNOX	§	
AND HERBERT KNOX	§	
	§	
V.	§	CA. NO. C-94-527
	§	
SANDOZ	§	
PHARMACEUTICAL	§	
CORPORATION	§	

ORDER PARTIALLY GRANTING PLAINTIFFS' MOTION FOR RECONSIDERATION, PARTIALLY GRANTING DEFENDANT'S MOTION IN LIMINE, AND PARTIALLY GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiffs have brought products liability , negligence, and breach of implied warranty claims against Defendant drug manufacturer for injuries, including dystonia, hypotension, seizures, headaches, and mental disturbances, allegedly resulting from Tracy Knox's ingestion of the drug Parlodel, the Sandoz trade name for bromocriptine mesylate. Ms. Knox's doctor prescribed this drug for lactation suppression following the birth of Plaintiffs' son.

Plaintiffs' expert, Dr. Stephen Inbody, M.D., provides Plaintiffs' only expert medical testimony concerning the alleged causal link between Parlodel and Ms. Knox's injuries. Defendant has filed a Motion in Limine to strike Dr. Inbody's testimony and has moved for summary judgment on the grounds that Dr. Inbody's testimony is inadmissible and hence causation is not provable. After a hearing at which Dr. Inbody testified at length about his medical opinions and methodology, this Court determined that Dr. Inbody's testimony failed to satisfy the requirements for the admissibility of expert testimony set forth in Daubert v. Merrell Dow Pharmaceutical, Inc., 113 S. Ct. 2786 (1993).

For the reasons set forth below, the Court denies Plaintiffs' Motion for Reconsideration of this ruling with respect to Dr. Inbody's testimony that Parlodel causes dystonia. The Court grants Defendant's Motion in Limine to the extent that it seeks exclusion of Dr. Inbody's testimony that Parlodel causes dystonia. The Court grants Defendant's Motion for Summary Judgment to the extent that Ms. Knox alleges that the drug caused her to have a stroke because Dr. Inbody testified that she did not stroke.

The Court grants Plaintiffs' Motion for Reconsideration to the extent that the Court may have excluded Dr. Inbody's testimony with respect to Ms. Knox's other conditions that are stated as possible adverse effects in Sandoz literature. The Court denies Defendant's Motion for Summary Judgment with respect to these other alleged conditions. The Court holds that Dr. Inbody may testify to Ms. Knox's medical condition and may state the causes of her conditions based on reasonable medical probability provided that any testimony concerning a

causal relationship between Parlodel and dystonia is excluded under Daubert for the reason discussed below. Wherever relief is not specifically granted, it is denied.

I. Plaintiffs' Motion for Reconsideration

A. Rule 702

In Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993), the United States Supreme Court articulated certain standards for the admissibility of expert testimony under Federal Rule of Civil Procedure 702. Pursuant to Rule 104(a), the trial judge must determine at the outset whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. Id. at 2796. In other words, the proffered evidence must be both reliable and relevant. Id. at 2795. Because Dr. Inbody's testimony in the present case is clearly relevant, the Court focuses on the issue of reliability. The knowledge offered must be "more than speculative belief or unsupported speculation." Id. The Supreme Court set forth the following nonexclusive list of factors to guide this inquiry:

(1) whether the theory can be (and has been) tested;

(2) whether the theory has been subjected to peer review and publication;

(3) consideration of the known or potential rate of error of a particular scientific technique;

(4) general acceptance in the relevant scientific community.

Id. at 2796-97. In determining the admissibility of scientific evidence, the court's focus "must be solely on principles and methodology, not on the conclusions they generate." Id. at 2797.

Based on the testimony and record, the Court finds that there is a significant lack of evidence of tests, publication, or general acceptance of Dr. Inbody's theory. Dr. Inbody bases his scientific analysis on various factors, including analogies he draws between the effects of the drugs in Parkinson's patients and the injuries to Ms. Knox, analogies he draws between Parlodel and other types of drugs that cause tardive dyskinesia, his knowledge and personal experience with Parlodel in Parkinson's patients, his familiarity with and treatment of Ms. Knox's condition, and the elimination of other causes. Dr. Inbody has reviewed certain written materials, including two articles. One article involved a study of bromocriptine-induced dystonia in stroke patients, and the other dealt with a study of bromocriptine-induced dystonic reactions in primates. Neither study provides direct support for the conclusion that Parlodel can cause tardive, sustained dystonia in non-Parkinson's patients. Based on the above evidence, Dr. Inbody concludes that Parlodel more likely than not caused Ms. Knox's dystonia.

Dr. Inbody admits that there are no studies on his theory that Parlodel can cause dystonia in non-Parkinson's patients. He further testified that Ms. Knox's condition "may be a very, very rare complication." Dr. Inbody stated that idiopathic, or unknown, causes top the list of causes of dystonia, although

that category is shrinking. He asserts that doctors are still in a "very steep part of our learning curve" with respect to dystonia, a controversial area of medicine. Other causes of dystonia mentioned to Dr. Inbody include other drugs and genetic disorders, both of which could apply to Ms. Knox.

Dr. Inbody testified that Ms. Knox is the only patient he has seen with a sustained tardive dystonic reaction following the ingestion of Parlodel. He recognized that his theory is "semi-speculative and inferred by reactions to drugs." Although Dr. Inbody believes his hypothesis ultimately will prove correct, he explained that he believes "it requires a combination of things, it's got to be infrequent, but, it may be a genetic predisposition on top of a drug effect, just like most idiosyncratic reactions to medications, you know that run through families."

Although Daubert creates a flexible approach, the testimony in the present case does not clearly satisfy any of the factors discussed in Daubert. Any tests and studies provide only analogies from which Dr. Inbody was able to draw his conclusion concerning the relationship between Parlodel and dystonia. The Fifth Circuit has emphasized in dicta the importance of testing and peer review and publication under Daubert. Wheat v. Pfizer, Inc., 31 F.3d 340, 343 (5th Cir. 1994). The theory that Parlodel causes dystonia in non-Parkinson's patients has not been tested or subjected to peer review and publication. Plaintiffs emphasize that the novelty of this theory prevents widespread acceptance at this stage. In the absence of other strong indicia of reliability, however, the Court finds that this testimony does not satisfy the legal standards set forth in Daubert.

B. Rule 403

In addition, the Court also finds that Federal Rule of Civil Procedure 403 provides additional support for the exclusion of Dr. Inbody's testimony on the causal link between Parlodel and dystonia because the probative value of the testimony is substantially outweighed by the danger of unfair prejudice. Fed. R. Civ. P. 403. In Daubert, the Supreme Court emphasized that judges should consider other applicable rules, including Rule 403, as they assess the admissibility of expert testimony under Rule 702. The Fifth Circuit has noted that Daubert's flexible approach may require increased use of Rule 403, especially when novel or controversial testimony is involved. United States v. Posado, 57 F.3d 428, 435 (5th Cir. 1995). Because Dr. Inbody would be testifying as an expert concerning a novel theory about which there are no direct studies or literature, the Court holds that Rule 403 provides an additional basis for the exclusion of this testimony.

C. Conclusion

The Supreme Court emphasized the critical differences between "the quest for truth in the courtroom and the quest for truth in the laboratory." Daubert, 113 S. Ct. at 2798. The Court's holding comports with one of the Supreme Court's concluding observations:

> We recognize that in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance

> that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.

Id. at 2798-99. This Court does not seek to question Dr. Inbody's medical conclusions. In carrying out the gatekeeping role imposed upon it, however, the Court must ensure that the underlying methodology meets established legal standards. As a matter of medicine, Dr. Inbody's theory will inform his treatment of Ms. Knox's condition. As a matter of law, however, the theory fails to satisfy the legal standards required to impose liability on Defendant. The Court holds that Dr. Inbody's testimony on the causal relationship between Parlodel and dystonia is inadmissible and denies Plaintiffs' Motion for Reconsideration on this issue.

To the extent that Dr. Inbody can testify based on reasonable medical probability that Parlodel caused Ms. Knox's other alleged conditions, the Court will permit this testimony because the publication of these possible adverse effects in Sandoz literature constitutes sufficient evidence of causation to survive summary judgment on this issue.

II. Defendant's Motion for Summary Judgment

Defendant has moved for summary judgment primarily on the grounds that Plaintiffs have failed to provide sufficient admissible evidence that Parlodel caused Plaintiffs' injuries. A court will grant summary judgment if the evidence shows that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. Fed.

R. Civ. P. 56(c). A party seeking summary judgment bears the initial burden of informing the court of the basis for its motion and of identifying those portions of the record and affidavits which evidence an absence of material fact. Celotex Corp. V. Catrett, 106 S. Ct. 2548, 2553 (1986). Once the movant has met its burden, the nonmovant who will have the burden of proof at trial must come forward with summary judgment evidence establishing the existence of a genuine issue. Duffy v. Leading Edge Products, Inc., 44 F.3d 308, 312 (5th Cir. 1995) (citing Celotex, 106 S. Ct. at 2552). The Court must view all inferences from the evidence in the light most favorable to the nonmovant. Anderson v. Liberty Lobby, Inc., 106 S. Ct. 2505, 2513 (1986).

Plaintiffs' primary injury is the dystonic reaction that has left one side of her face immobilized. The Court has excluded the testimony of Plaintiff's only expert witness on the causal link between the ingestion of Parlodel in non-Parkinson's patients and the occurrence of dystonia. In spite of the Court's extension of the deadlines to permit Plaintiffs to procure additional experts, Plaintiffs were unable to locate other witnesses who could provide evidence of the causal link between Parlodel and Ms. Knox's condition.

Dr. Inbody testified that a dystonic reaction following the ingestion of Parlodel by a non-Parkinson's patient is very rare and that dystonia has may possible causes, including a large category of unknown causes. The Court finds the evidence insufficient to establish that Parlodel is either a proximate or a producing cause of Mrs. Knox's dystonia. Plaintiffs' evidence that Parlodel caused the dystonia is insufficient to survive summary judgment.

Regardless of these considerations, the exclusion of Dr. Inbody's testimony on the causal relationship between Parlodel and dystonia eliminates Plaintiffs' only expert witness on this issue. In products liability cases where the cause of the injury has not been firmly established and is not readily ascertainable from general experience and common sense, a jury ordinarily cannot determine scientific or medical causation without the assistance of experts. *See* Merrell Dow Pharmaceuticals, Inc. v. Havner, 907 S.W.2d 535, 551 (Tex. App.-- Corpus Christi 1994, writ granted) (en banc) (citing Lenger v. Physician's Gen. Hosp., Inc., 455 S.W.2d 703, 705 (Tex. 1970). As a result, Plaintiffs cannot adequately prove causation of dystonia in the absence of Dr. Inbody's testimony.

Because the record fails to provide sufficient evidence of causation of dystonia without this testimony, the Court grants Defendant's Motion for Summary Judgment with respect to Plaintiffs' claims that Parlodel caused Ms. Knox's dystonia. The Court denies Defendant's Motion for Summary Judgment on Ms. Knox's other conditions that are listed as possible adverse effects in Sandoz literature.

The Court believes that this order concludes all outstanding motions with respect to summary judgment. To the extent that the parties wish to file any other dispositive motions, the Court orders such motions to be filed within 15 days.

ORDERED this 10th day of June, 1996.

/s/ H.W. Head, Jr.
H.W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

ENTERED ON DOCKET
JUN. 11, 1996
BY MICHAEL N. MILBY,
CLERK OF COURT

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

TRACY DIONNE KNOX, ET AL.,	§	CIVIL ACTION
PLAINTIFFS	§	CA-C-94-527
VS.	§	CORPUS CHRISTI, TX
	§	JULY 11, 1996
SANDOZ PHARMACEUTICALS, INC.,	§	9:17 A.M.
DEFENDANT	§	

.....

EXCERPTS OF TRANSCRIPT OF CIVIL DOCKET

Page 9 - lines 13-25 through
Page 10, lines 1-2

MS. VANCE: And yet the testimony is stronger on dystonia than it is on any of these so-called new complaints. And I can go --

THE COURT: Well, at least he gives his thoughts on it.

MS. VANCE: On dystonia.

THE COURT: That's right, and he is, I mean, I, for purposes of the record, if the Circuit would like to know what

I was thinking on that, I tried to put it in the order, and while he thought, while the Doctor was expressing himself in a logical fashion, going from one level of observation and thought to another, my judgment was that if I were to rely upon the signposts of Daubert that his theory I think failed on every one of those four criteria that Daubert likes us to examine. So, that's where we are. Mr. Wavell?

APPENDIX D

[Filed Jul. 15, 1996]

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

TRACY DIONNE KNOX, ET AL	§	
	§	
V.	§	CA. NO. C-94-527
	§	
SANDOZ	§	
PHARMACEUTICALS	§	
CORPORATION	§	

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' FIRST AMENDED ORIGINAL COMPLAINT

For the reasons discussed at the hearing on July 11, 1996, the Court grants Defendant's Motion for Summary Judgment on Plaintiffs' First Amended Original Complaint.

ORDERED this 11th day of July, 1996.

/s/ H.W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

ENTERED ON DOCKET
JUL. 15, 1996
BY MICHAEL N. MILBY,
CLERK OF COURT

APPENDIX E

[Filed Jul. 15, 1996]

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

TRACY DIONNE KNOX	§	
AND HERBERT KNOX	§	
	§	
V.	§	CA. NO. C-94-527
	§	
SANDOZ	§	
PHARMACEUTICALS	§	
CORPORATION	§	

FINAL JUDGMENT

The Court has granted summary judgment in favor of Defendant. The Court renders final judgment in favor of Defendant that Plaintiff take nothing from Defendant. Defendant is awarded its costs.

ORDERED this 11th day of July, 1996.

/s/ H.W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

ENTERED ON DOCKET
JUL. 15, 1996
BY MICHAEL N. MILBY,
CLERK OF COURT

APPENDIX F

[Filed Mar. 10, 1997]

UNITED STATES COURT OF APPEALS
for the Fifth Circuit

No. 96-40671

TRACY DIONNE KNOX ET AL.,
Plaintiffs-Appellants,

VERSUS

SANDOZ PHARMACEUTICALS CORPORATION,
Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Texas
(C-94-CV-527)

BEFORE: DAVIS, SMITH and DUHÈ, Circuit Judges.

PER CURIAM:*

The only issue presented on appeal is whether, following a Daubert hearing, the district court erred in refusing to permit plaintiffs' medical expert to give an opinion on causation in this case.

After reviewing the record, we are persuaded that the district court did not abuse its discretion.

AFFIRMED.

ENTERED FOR THE COURT:

By: /s/ DAVIS
/s/ SMITH
/s/ DUHÈ

ENTERED ON DOCKET
MAR. 10, 1997
BY CHARLES R. FULBRUGE, III,
CLERK OF US COURT OF APPEALS

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* Pursuant to Local Rule 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in Local Rule 47.5.4.

APPENDIX G

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

TRACY DIONNE KNOX, ET AL,	§	CIVIL ACTION
	§	
	§	CA-C-94-527
VS.	§	
	§	CORPUS CHRISTI, TX
	§	JANUARY 4, 1996
SANDOZ PHARMACEUTICALS, INC.	§	10:31 A.M.
	§	
	§	

EXCERPTS FROM VOLUME II OF II
TRANSCRIPT OF DAUBERT HEARING

Page 2-11
Lines 15-21

THE COURT: Counsel, we are here to discuss whether or not Dr. Inbody is going to be allowed to testify under the rules of the Daubert/Merrell Dow case.

MR. WAVELL: I understand, but also --

THE COURT: The United States Supreme Court has set some very stringent guidelines on the admission of scientific testimony.

Page 2-58 - line 16 through
Page 2-60 - line 7

THE COURT: Do you think it's really fair to characterize his belief in what he said as his speculation?

MS. VANCE: That's his word, Judge.

THE COURT: It is true that he has used and did use the word semi-speculation, and I wondered about what it meant too, but in the context of all of his testimony, did he not say that, "I have examined this lady's condition and I have gone down basically the journey of believing that she may have had some sort of psychosomatic or conversion or whatever cause to eliminating all of those and arriving at the conclusion that what she has is a reaction to Parlodel, and I got there by giving it some thought, that thought being she has the same symptoms that Parkinsonian patients have, by observing the rebound effect"? This doctor is not some charlatan.

MS. VANCE: You're right.

THE COURT: This is an extremely able, respected physician who was careful in his diagnosis, conclusion and concern for his patient, who in fact has not only diagnosed this cause but believes it to be a cause so much so that that's the way he treats his patient, I mean he believes it to such a degree that he has implemented that belief in the course of her treatment. I mean it's just not, "This is my opinion, I'm an expert, now I'm picking up my expert fee and I'm going home." This is a lady that he's treated. So, and he has impeccable credentials as a neurologist. I mean I haven't, don't

know many neurologists but it sounds like that he has impeccable credentials. I don't have him to compare with other neurologists but he certainly is, what is it, Chief Resident of Baylor Medical College? I mean, I didn't know what institution Baylor was associated with, perhaps none, but it is certainly well known to me as being a very fine institution. He has enormous experience. He has been a classroom teacher, he's been a researcher, he's, the man knows what he's talking about when he performs his doctor's, as a doctor of neurology. Anybody that had him would be, I think, darned lucky to have him as a physician, and I haven't seen anything to the contrary and you haven't offered me anybody that says to the contrary. Now, I don't know that that resolves the answer. I don't know that that resolves it. It might resolve it. What I was trying to ask plaintiff was to speak in terms of the language that Daubert suggests that a judge should examine. My approach was not accepted.

APPENDIX H

Federal Rules of Evidence

Rule 104

Preliminary Questions

(a) **Questions of admissibility generally**. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) **Relevancy conditioned on fact**. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

(c) **Hearing of jury**. Hearings on the admissibility of confessions shall in all cases be conducted out of the hearing of the jury. Hearings on othe preliminary matters shall be so conducted when the interests of justice require, or when an accused is a witness and so requests.

(d) **Testimony by accused**. The accused does not, by testifying upon a preliminary matter, become subject to cross-examination as to other issues in the case.

(e) **Weight and credibility**. This rule does not limit the right of a party to introduce before the jury evidence relevant to weight or credibility.
(Pub.L. 93-595, § 1, Jan. 2, 1975, 88 Stat. 1930; Mar. 2, 1987, eff. Oct. 1, 1987.)

* * * *

Rule 702

Testimony by Experts

In scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.
(Pub.L. 93-595, § 1, Jan. 2, 1975, 88 Stat. 1937.)

OPPOSITION

BRIEF

(2)

Supreme Court, U.S.
FILED
JUL 10 1997
OFFICE OF THE CLERK

No. 96-1953

IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

TRACY DIONNE KNOX and HERBERT KNOX,
Petitioners,
v.
SANDOZ PHARMACEUTICALS CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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21pp

QUESTION PRESENTED

Whether the standard set forth by this Court in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and Fed. R. Evid. 702 is insufficient to address novel scientific theories that are too new or of too limited interest to be published such that an exception to *Daubert* or a new rule should be created to address this type of novel scientific evidence.

PARTIES TO THE PROCEEDINGS

The names of all parties in the district court and the court of appeals are listed in the caption. Respondent Sandoz Pharmaceuticals Corporation ("Sandoz") is now known as Novartis Pharmaceutical Corporation. Novartis Pharmaceutical Corporation is an indirect subsidiary of Novartis AG. The holding companies between Novartis Pharmaceutical Corporation and Novartis AG are: Novartis Finance Corporation, Novartis Corporation, and Novartis Holding AG. Novartis Pharmaceutical Corporation owns the majority of stock of Novartis Biotech Partnership, Inc. and the remaining stock is owned by a direct subsidiary of Novartis AG. Novartis Pharmaceutical Corporation also owns approximately 46 percent of Chiron Corporation.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

No. 96-1953

TRACY DIONNE KNOX and HERBERT KNOX,
Petitioners,

v.

SANDOZ PHARMACEUTICALS CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

---

RESPONDENT'S BRIEF IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 20-21) is unreported. The decisions of the district court (Pet. App. 2-19) are unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 20-21) was entered on March 10, 1997. A petition for a writ of certiorari was filed on June 9, 1997, and docketed on June 10, 1997. The jurisdiction of the Court is invoked under 28 U.S.C. § 1254(1).

RULES INVOLVED

Rules 104, 201, 402, 403, and 702 of the Federal Rules of Evidence are reproduced at Resp. App. 1a-3a.

STATEMENT

During May of 1994, after giving birth to her son, Petitioner Tracy Knox was given a fourteen-day prescription of Parlodel® for the prevention of physiological lactation. Parlodel® is a trade name for bromocriptine mesylate, which is manufactured by Respondent Sandoz Pharmaceuticals Corporation ("Sandoz"). During August of 1994, Tracy Knox suffered from what were characterized as stroke-like symptoms. Dr. Steven B. Inbody, a neurologist, diagnosed Tracy Knox's condition as tardive hemidystonia.

A. District Court Proceedings

Petitioners brought suit against Sandoz alleging product liability, negligence, and breach of implied warranty associated with the manufacture and sale of Parlodel®. Petitioners filed suit in Nueces County, Texas District Court, on October 28, 1994. On December 2, 1994, Sandoz removed the case to the United States District Court for the Southern District of Texas on the basis of diversity jurisdiction, 28 U.S.C. § 1332.

To support their theory that the Parlodel® was the cause of Tracy Knox's condition, Petitioners proffered only the testimony of Dr. Inbody. Respondent filed a motion *in limine* to strike Dr. Inbody's testimony on the basis that it was inadmissible under the standards for expert testimony set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). After a *Daubert* hearing, the district court excluded, as scientifically unreliable under Fed. R. Evid. 702, Dr. Inbody's expert testimony that Tracy Knox's tardive dystonia was caused by her ingestion of Parlodel®.[1]

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[1] As an additional basis for excluding Dr. Inbody's testimony, the trial court relied on Fed. R. Evid. 403. The trial judge found that Dr. Inbody's "testimony on the causal link between Parlodel® and dystonia [should be excluded] because the probative value of the testimony is substantially outweighed by the danger of unfair preju-

Because Dr. Inbody's opinion was "clearly relevant," the trial court focused on the reliability of the testimony. (Pet. App. 8). The court found:

> Dr. Inbody base[d] his scientific analysis on various factors, including analogies he draws between the effects of the drugs in Parkinson's patients and the injuries to Ms. Knox, analogies he draws between Parlodel® and other types of drugs that cause tardive dyskinesia, his knowledge and personal experience with Parlodel® in Parkinson's patients, his familiarity with and treatment of Ms. Knox's condition and the elimination of other causes.

(Pet. App. 9). The trial judge determined that there were no studies, including the two articles reviewed by Dr. Inbody, supporting the theory that "Parlodel® can cause tardive, sustained dystonia in non-Parkinson's patients." (Pet. App. 9). Moreover, the trial court found that although Dr. Inbody thinks that "Parlodel® more likely than not caused Ms. Knox dystonia," Dr. Inbody acknowledged that there were other causes of dystonia "which could apply to Ms. Knox." (Pet. App. 9-10).

In ruling that Dr. Inbody's testimony was inadmissible, the trial judge expressly assessed the testimony against this Court's *Daubert* standard:

> Although *Daubert* creates a flexible approach, the testimony in the present case does not clearly satisfy any of the factors discussed in *Daubert*. Any tests and studies provide only analogies from which Dr. Inbody was able to draw his conclusion concerning the relationship between Parlodel® and dystonia. The Fifth Circuit has emphasized in dicta the importance of testing and peer review and publication under *Daubert*. *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994). The theory that Parlodel® causes

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dice"; i.e., "Dr. Inbody would be testifying as an expert concerning a novel theory about which there are no direct studies or literature. . . ." (Pet. App. 11).

> dystonia in non-Parkinson's patients has not been tested or subjected to peer review and publication. Plaintiffs emphasize that the novelty of this theory prevents widespread acceptance at this stage. In the absence of strong indicia of reliability, however, the Court finds that this testimony does not satisfy the legal standards set forth in *Daubert*.

(Pet. App. 10).

Because Petitioners were unable to establish a causal link between Tracy Knox's condition and Parlodel®, the trial court granted summary judgment in favor of Respondent. Final judgment was entered by the trial court on July 11, 1996.

B. Court of Appeals Proceedings

On July 19, 1996, Petitioners filed a notice of appeal to the United States Court of Appeals for the Fifth Circuit. After oral argument, the court of appeals issued its order on March 10, 1997, affirming the decision of the trial court.

REASONS FOR DENYING THE WRIT

This case does not warrant the Court exercising its extraordinary and discretionary jurisdiction. The decision of the district court and court of appeals does not conflict with any decision of this Court or any other court. Nor does the petition present an important issue of law which needs to be addressed by this Court. Petitioners simply seek reconsideration of the standards for the admissibility of expert testimony set forth only four years ago in this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).[2]

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[2] The issue presented by Petitioners is distinguishable from that presently before the Court in *General Electric Co. v. Joiner*, No. 96-188. In this petition, Petitioners are requesting that the Court revisit the standard for admitting expert testimony under *Daubert*. The issue presented to the Court in *Joiner* is what standard of

In *Daubert*, this Court held that the admissibility of expert testimony regarding novel scientific evidence is specifically governed by Fed. R. Evid. 702, and more generally, by other Federal Rules of Evidence such as 104, 402, and 403.[3] The cornerstone of the Court's opinion in *Daubert*, and the fundamental principle underlying the rule, is that juries should not be asked to render decisions on scientific issues unless provided with evidence that is scientifically reliable, or, in other words, is "based upon scientific validity." *Daubert*, 509 U.S. at 509 n.9. The Court held that trial judges must exercise a gatekeeping role to assure that only evidence that is relevant and scientifically reliable reaches a jury. *Id.* at 589. In determining whether the testimony is scientifically reliable, "the district court [must] consider whether the testimony has been subject to the scientific method; it must rule out 'subjective belief or unsupported speculation.'" *Porter v. Whitehall Laboratories, Inc.*, 9 F.3d 607, 614 (7th Cir. 1993). In short, the trial court's task "is to analyze not what the experts say, but what basis they have for saying it." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995), *cert. denied*, —— U.S. ——, 116 S.Ct. 189 (1995).[4]

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review should be exercised by the court of appeals in reviewing the trial court's decision to admit or exclude expert testimony pursuant to Fed. R. Evid. 702 and *Daubert*.

[3] Fed. R. Evid. 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

[4] Petitioners also rely on what they perceive to be the failure of Respondent to provide scientific evidence to rebut Dr. Inbody's opinion. Respondent, however, is not required to provide scientific evidence to rebut the testimony of the opposing party's expert. "Rather, the party presenting the expert must show that the experts findings are based on sound science, and this will require some objective, independent validation of the experts methodologies." *Daubert*, 43 F.3d at 1316.

To help trial judges in such an undertaking, this Court set forth a guiding list of factors that the trial judges should consider in deciding to admit or exclude the expert testimony. These factors are whether the theory (1) "can be (and has been) tested"; (2) "has been subjected to peer review and publication"; (3) has a "known or potential rate or error"; and (4) is "generally accepted in the relevant scientific community." *Daubert*, 509 U.S. at 593-94. Petitioners contend that expert opinion is inadmissible under *Daubert* only if one of these specific factors is left unsatisfied. This contention, however, is not consistent with *Daubert*. The Court specifically noted that these factors are neither exclusive nor applicable in every situation. *Daubert*, 509 U.S. at 593-95. Instead, these factors are simply meant to assist the trial court in determining "whether the analysis undergirding the expert's testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Daubert*, 43 F.3d at 1317. This type of review seeks "to make sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work." *Rosen v. Ciba-Geigy*, 78 F.3d 316, 318 (7th Cir. 1996), *cert. denied*, —— U.S. ——, 117 S.Ct. 73 (1996). In keeping with the express directive of this Court, Petitioner's protestations notwithstanding, the circuit courts of appeal have acknowledged that the inquiry into scientific reliability is a flexible one.[5]

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[5] *United States v. Jones*, 107 F.3d 1147, 1156-58 (6th Cir.), *cert. denied*, —— U.S. ——, 1997 U.S. LEXIS 4185 (June 27, 1997); *Ambrosini v. Labarraque*, 101 F.3d 129, 134 (D.C. Cir. 1996), *cert. dismissed, sub nom., Upjohn Co. v. Ambrosini*, —— U.S. ——, 117 S.Ct. 1572 (1997); *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996) (*cert. pending* No. 96-1493); *Cummins v. Lyle Industrial*, 93 F.3d 362, 368 (7th Cir. 1996); *Compton v. Subaru of America*, 82 F.3d 1513, 1518 (10th Cir.), *cert. denied*, —— U.S. ——, 117 S.Ct. 611 (1996); *Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995), *cert. denied*, —— U.S. ——, 116 S. Ct. 1869 (1996); *United States v. Posado*, 57 F.3d 428, 435 (5th Cir. 1995); *Daubert*

Petitioners claim that the facts of this case are unique and fall within a gap left open by *Daubert*.[6] Petitioners ask that *Daubert* be revisited to address scenarios where a scientific theory has not been tested or subjected to study because the theory is too new or the condition rarely occurs. Petitioners argue that such theories cannot possibly meet the four factors of *Daubert*. But the argument misses the point: *Daubert* explicitly applies across the spectrum of scientific theory to both well-established principles and novel, innovative theories.[7] *Daubert*, 509 U.S. at 593 n.11 ("[W]e do not read the requirements of Rule 702 to apply specifically or exclusively to unconventional evidence. Of course, well-established propositions are less likely to be challenged than those that are novel, and they are more handily defended."). The key inquiry required by *Daubert* is whether the expert testimony is reliable (scientifically valid) and relevant. As recognized by the trial court, to determine whether the scientific theory is reliable, "[t]he focus [of the trial court's inquiry] . . . must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595.

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v. Merrell Dow Pharmaceuticals, 43 F.3d 1311, 1316-17 (9th Cir.), *cert. denied*, —— U.S. ——, 116 S. Ct. 189 (1995); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994), *cert. denied, sub nom., General Elec. Co. v. Ingram*, —— U.S. ——, 115 S. Ct. 1253 (1995); *Pioneer Hi-Bred International v. Holden Foundation Seeds, Inc.*, 35 F.3d 1226, 1230 (8th Cir. 1994).

[6] Petitioners rely heavily on the differences between the facts involved in this case and the facts involved in *Daubert*. To the extent such factual "differences" exist, they are irrelevant; the standards for admissibility under Fed. R. Evid. 702, relevance and scientific reliability, are applicable to all scientific evidence. Moreover, the fundamental nature of the challenged testimony in Daubert —misuse of expert causation opinion in a pharmaceutical liability case—is identical to that at issue here.

[7] If a scientific principle is well established, it need not undergo the *Daubert* analysis but can be the subject of judicial notice under Fed. R. Evid. 201. *Daubert*, 509 U.S. at 593 n.11.

(Pet. App. 2-3).[8] Since *Daubert* was handed down, federal judges have shown that they "possess the capacity to undertake this review" and do not need this Court to provide "a definitive checklist or test" to address every factual situation that arises.[9] *Daubert*, 509 U.S. at 592.

Petitioners also contend that this case is important because of its obscurity. Putting aside whether "obscurity" makes a case worthy of review, in actuality, dozens of cases have excluded expert testimony because of the lack of testing, study, or other indications that the scientific theory is reliable. *See, e.g., Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194 (5th Cir. 1996) (expert testimony properly excluded due to lack of scientific evidence showing that exposure to ethylene oxide caused brain cancer); *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1159 (4th Cir. 1996) (expert testimony that AVJet vapors caused plaintiff's chronic illness was not " 'supported by appropriate validation' " and was properly excluded), (*cert. pending* No. 96-1493); *Rosen*, 78 F.3d at 319 (dis-

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[8] The trial judge stated:

> The Court does not seek to question Dr. Inbody's medical conclusions. In carrying out the gatekeeping role imposed upon it, however, the Court must ensure that the underlying methodology meets established legal standards. As a matter of medicine, Dr. Inbody's theory will inform his treatment of Ms. Knox's condition. As a matter of law, however, the theory fails to satisfy the legal standards required to impose liability on Defendant.

(Pet. App. 12).

[9] Petitioners allege that the trial judge disregarded this Court's emphasis that "[t]he inquiry envisioned by Rule 702 is . . . a flexible one." *Daubert*, 509 U.S. at 594. This allegation is contrary to the record. The trial judge did not limit his review of Dr. Inbody's testimony to the four factors listed in *Daubert*. Indeed, the trial judge, after noting that Dr. Inbody's theory had not been subject to testing or peer review, stated, "[i]n the absence of other strong indicia of reliability, however, the court finds that this testimony does not satisfy the legal standards set forth in *Daubert*." (Pet. App. 10).

tinguished cardiologist's theory that the use of a nicotine patch was the cause of a heart attack was properly excluded because of the lack of "any experimental, statistical, or other scientific data from which such a causal relation might be inferred or which might be used to test a hypothesis founded on theory."); *Wright v. Willamette Industrial, Inc.*, 91 F.3d 1105, 1107-08 (8th Cir. 1996) (expert testimony that plaintiffs' various symptoms were caused by exposure to formaldehyde should have been excluded "because it was not based on scientific knowledge."); *Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 596 (9th Cir. 1996) (expert testimony that the use of Clomid, a fertility drug, caused birth defect was properly excluded. "Dr. Done has seen fit to 'pick and chose' [sic] from the scientific landscape and present the Court with what he believes the final picture looks like. This is hardly scientific."); *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090, 1106 (7th Cir.) (expert's theory excluded, not because he was a " 'lone voice,' " but because no scientific authority "indicat[ing] that radiation-induced cataracts can be identified by mere observation."), *cert. denied*, 512 U.S. 1222 (1994); *Porter v. Whitehall Laboratories, Inc.*, 9 F.3d 607, 614 (7th Cir. 1993) (expert testimony that ibuprofen caused rapidly progressive glomerulonephritis properly excluded because there were no "studies, records, or data" showing that the theory was "well-grounded in the scientific method.").

Petitioners further allege that the trial court misapplied *Daubert* by "plac[ing] a higher burden of scientific proof than is required by the rules of evidence." (Pet. 9). Specifically, Petitioners claim that the district court "rigidly" and "arbitrarily" applied the signposts set forth in *Daubert* to exclude Dr. Inbody's testimony. This contention, if it were true, would not warrant this Court's review because the district court's alleged improper application of the standard for admitting scientific testimony turns on facts specific to this case and was subject to review by the court of appeals. Indeed, Petitioners pur-

sued that avenue of relief but to no avail. In essence, Petitioners are seeking this Court to engage in a third review of Dr. Inbody's testimony in their effort to establish scientific reliability. This is not a purpose served by granting certiorari: "The jurisdiction [to bring up cases by certiorari] was not conferred upon this Court merely to give the defeated party in the Circuit Court of Appeals another hearing." *Magnum Import Co., Inc. v. Coty*, 262 U.S. 159, 163 (1923); *Ross v. Moffitt*, 417 U.S. 600, 620 (1974) (Douglas, J., dissenting); *Jones v. Alfred H. Mayer Co.*, 392 U.S. 409, 478 (1968) (Harlan, J., dissenting); *Rice v. Soux City Mem. Park Cemetery Inc.*, 349 U.S. 70, 74 (1955).

In sum, Petitioners simply disagree with the trial court's application of the *Daubert* standards to the facts of this case. Petitioners believe that Dr. Inbody's testimony provides a reasonable theory to show that the ingestion of Parlodel® caused Petitioner Tracy Knox's medical condition. But Dr. Inbody's theory, "while expressing what may be an insightful, even an inspired, hunch concerning the cause of [Tracy Knox's condition] lacks scientific rigor." *Rosen*, 78 F.3d at 319. Petitioners fail to recognize that "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Id.* Therefore, in the absence of evidence showing that the methodologies and principles used by the expert are reliable, Fed. R. Evid. 702 and *Daubert* require that the expert's testimony be excluded.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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July 10, 1997

APPENDIX

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FEDERAL RULES OF EVIDENCE

Rule 104. Preliminary Questions

(a) Questions of admissibility generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) Relevancy conditioned on fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

(c) Hearing of jury. Hearings on the admissibility of confessions shall in all cases be conducted out of the hearing of the jury. Hearings on other preliminary matters shall be so conducted when the interests of justice require, or when an accused is a witness and so requests.

(d) Testimony by accused. The accused does not, by testifying upon a preliminary matter, become subject to cross-examination as to other issues in the case.

(e) Weight and credibility. This rule does not limit the right of a party to introduce before the jury evidence relevant to weight or credibility.

(Pub.L. 93-595, § 1, Jan. 2, 1975, 88 Stat.1930; Mar. 2, 1987, eff. Oct. 1, 1987.)

Rule 201. Judicial Notice of Adjudicative Facts

(a) Scope of rule. This rule governs only judicial notice of adjudicative facts.

(b) Kinds of facts. A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

(c) When discretionary. A court may take judicial notice, whether requested or not.

(d) When mandatory. A court shall take judicial notice if requested by a party and supplied with the necessary information.

(e) Opportunity to be heard. A party is entitled upon timely request to an opportunity to be heard as to the propriety of taking judicial notice and the tenor of the matter noticed. In the absence of prior notification, the request may be made after judicial notice has been taken.

(f) Time of taking notice. Judicial notice may be taken at any stage of the proceeding.

(g) Instructing jury. In a civil action or proceeding, the court shall instruct the jury to accept as conclusive any fact judicially noticed. In a criminal case, the court shall instruct the jury that it may, but is not required to, accept as conclusive any fact judicially noticed.

(Pub.L. 93-595, § 1, Jan. 2, 1975, 88 Stat. 1930.)

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

(Pub.L. 93-595, § 1, Jan. 2, 1975, 88 Stat. 1931.)

Rule 403. Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion, or Waste of Time

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

(Pub.L. 93-595, § 1, Jan. 2, 1975, 88 Stat. 1932.)

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

(Pub.L. 93-595, § 1, Jan. 2, 1975, 88 Stat. 1937.)